# Curriculum Vitae for Dr. W. Jeffrey Allard

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Education	B.S., Pre-Veterinary Medicine, [] University of New Hampshire, Durham, New Hampshire. Graduated Cum Laude			
	M.S., Immunology, [] Idaho State University, Pocatello, Idaho Thesis Advisor: []			
	Ph.D., Biochemistry, [] Dartm Hanover, New Hampshire Thesis Advisor: [			

# Research and Professional Experience

12/04-Present Vice President and Chief Scientific Officer

Fujirebio Diagnostics, Malvern, PA

Responsible for evaluation of new technologies, expansion of global partnerships, and scientific management of relationships with IVD partners. Responsible for research and development of new biomarkers, including immunoassay and RT-PCR-based configurations, for application in oncology and cardiovascular diseases. Developed a Product Development Process for all new product applications. Manage all aspects of clinical trial design and management including development of prospective multicenter studies of biomarker panels in differential diagnosis and cancer detection. Manage Regulatory Affairs including 510(k) and PMA products reviewed by the Office of *in vitro* Device Evaluation (OIVD) within CDRH. Manage Immunoassay Product Development group with

responsibility for product development under contract with various automated IVD partners, and manufacturing technical support.

10/00-11/04 Vice President, Clinical Research and Development, Immunicon Corporation, Huntingdon Valley, PA.

> Responsible for all phases of clinical research and development including the design and management of a program to establish clinical validity and utility of circulating tumor cells in patients with cancer, and circulating endothelial cells in patients with cancer and cardiovascular disease. Designed clinical projects, developed timelines and budgets, and hired and managed clinical staff. Communicate objectives and progress to Senior Management and to partners for Sales and Marketing, particularly J&J (Veridex, LLC). Initiated and managed prospective, multicenter, double blind, statistically powered clinical trials in colorectal, lung, prostate and breast cancers. Provided clinical data for FDA submissions on instrumentation and clinical utility claims. Established and managed clinical laboratory with 8 employees to process > 500 blood samples per month according to GLP requirements. Established and managed phlebotomy facility to obtain blood samples for internal R&D under GCP, IRB approved protocols, and Informed Consent (1000 – 1500 blood samples per month from >100 donors). Established program to obtain blood samples prospectively from cancer centers for internal R&D.

3/00-10/00 Research Fellow, Director of Clinical and Regulatory Oncology, Diagnostic Oncology Group, Bayer Corporation, Business Group Diagnostics, Tarrytown, NY

> Manage Clinical Research trials in prostate and breast cancers. Manage clinical trials and submissions to FDA for automated tumor marker assays including complexed PSA, HER-2/neu, CA 15-3, CA 125, CEA, AFP and PSA. As a member of Oncology Strategy Team, Design and implement pipeline strategy for novel and proprietary oncology assays.

Principal Scientist, Diagnostic Oncology, Manager, Clinical Research, Bayer Corporation, Business Group Diagnostics, Tarrytown, NY

Establish novel and proprietary assays for complexed PSA and HER-2/neu as a clinical standard of care. Manage clinical research trials worldwide with academic, research, and commercial laboratories. Develop Prostate Cancer Strategy. Interact with Disease Focused Marketing and Medical Marketing in Clinician Education and assay promotion. Work with Director of Clinical Oncology to manage collaboration with Oncogene

4/99 - 3/00

Science Diagnostics (OSDI). Manage FDA Clinical Trials, submissions, and US Launch of tumor markers. Participate in developing RUO/IUO/ASR policy and procedures.

# 4/96 – 4-99 Senior Staff Scientist, Bayer Corporation

Core Team Leader: Phase 4 for complexed PSA

Core Team Leader - Complexed PSA on Bayer Immuno 1<sup>™</sup> analyzer

Core Team Leader: Phase 4 for US Launch of CEA and PSA

Core Team Leader: US Launch of PSA, Phase 3 Core Team Leader: PSA PMA Project Team

R & D Core Team Member: US Launch of CEA, Phase 3

R & D Core Team Member: CEA PMA Project

Team Leader for discovery, feasibility, and all phases of product development for novel and proprietary assay for complexed PSA.

Designed and managed total of ten clinical trials including:

PSA screening and monitoring cPSA screening and monitoring

HER-2/neu

CA 15-3

CA 125 (Second look surgery and general monitoring claims)

CEA

**AFP** 

Managed four PMA submissions to FDA for cPSA for screening, total PSA for screening, CEA in monitoring, and PSA in monitoring. Managed six 510(k) tumor marker submissions to FDA for HER-2/neu, AFP, CA 15-3, CA 125 for second look surgery, and CA 125 for monitoring. All submissions cleared or approved.

Participated in management of the Bayer collaboration with Oncogene Science Diagnostics, Inc. as member of Steering Committee and on day to day basis.

# 11/91-3/96: Staff Scientist, Project Leader, Bayer Corporation

Responsible for research and product development programs on novel diagnostic markers for cancer and osteoporosis. ELISA kit development; development of monoclonal antibodies and recombinant proteins; establishment of Departmental patient specimen collection; collaborations with academic and research institutions on novel analytes and clinical research.

1988-1991 Clinical Systems, Diagnostics Division, E. I. du Pont de Nemours, Glasgow, DE 9/90-10/91: Project Leader Developed heterogeneous sandwich immunoassay for hCG for commercialization on aca® STAR. 4/88-9/90: Research Immunologist Designed and developed program in Bispecific Antibodies. Prepared bispecific monoclonal antibodies by quadroma fusions, developed purification procedures by ion-exchange HPLC, measured affinity constants, tested in novel immunoassay formats. [-----] Postdoctoral Scientist in the laboratory of [------] Merck Sharp and Dohme Research Laboratories, West Point, PA. Cloning of the human M1 muscarinic receptor, generation of anti-peptide antibodies to G proteins and their use in probing G protein function in normal and diabetic tissue. Purification of GTPase activating protein and functional analysis with ras mutants. [-----] Thesis research, Dept. of Biochemistry, Dartmouth Med. School Research Advisor: [------] Generation and characterization of monoclonal antibodies to the human glucose transporter and their use in analysis of transporter phosphorylation. [-----] Research Assistant in the laboratory of [-----] Dana - Farber Cancer Institute, Boston, Massachusetts. Generation and characterization of cloned cytolytic T lymphocytes and natural killer cells. [-----] Master's Degree Department of Microbiology and Biochemistry Idaho State University Research advisor: [------]

Investigations on the immunogenicity of a syngeneic tumor and its effects on lymphokine synthesis in nude mice.

# **Expertise:**

Clinical trials:

Protocol design, management, data evaluation IRB approvals, HIPAA compliance, Informed Consent Site selection, CRO management, data monitoring Database management GCP and GLP compliance

Regulatory Affairs:

PMA and 510(k) submissions and approval process Protocol development with FDA Analyte specific reagents IUO/RUO products

### Expertise (cont,)

**Product Development** 

Product development process, design and implementation Product design Product development including verification and validation Product launch

Diagnostic research program planning and management

Patient specimen collection and archiving

Phlebotomy program development and management

Clinical laboratory management and compliance with GLP and CLIA '88

Hybridoma/quadroma production and screening

Immunochemistry and binding constant measurements

Protein purification and separation techniques

Receptor binding and pharmacology

Peptide synthesis

### **Awards**

Individual Science and Technology Award, cPSA Assay, 1998.

Vice President's Outstanding Core Team Award Complexed PSA Core Team, 1997

R & D Achievement Award, US Introduction of PSA, 1996.

R & D Achievement Award, US Introduction of CEA, 1996.

Individual Science and Technology Award, CA 228 Assay, 1994.

Commitment to Excellence Award, hCG Immunoassay, aca Star Platform, 1991, E.I. Dupont, Medical Products Division.

### **Patents**

**Paners** 

- Allard, W. J. and Yeung, K. K. 2001. US Serial Number 6,309,846 B1. Diagnosis and monitoring of colon cancer patients by measurement of NCA 50/90 in blood.
- Allard, W.J., Yeung, K.K, and Zhou, Z. 2000. US Patent 6,107,049. Sandwich immunoassay determination of cPSA.
- Allard, W.J., Yeung, K.K, and Zhou, Z. 1999. US Patent 5,928,878. Differentiation of prostate cancer from BPH by assaying PSA-ACT.
- Allard, W.J., Zhou, Z., and Yeung, K.K. 1998. US Patent 5,840,501. Method to improve early detection of prostate cancer by measurement of prostate specific antigen in complex with protease inhibitors.
- Allard, W. J. and Yeung, K. K. 1997. US Patent 5,605,804. Diagnosis and monitoring of lung cancer patients by measurement of NCA 50/90 in blood.
- Barnett, T. R., Elting, T. J. and Allard, W. J. 1997. US Patent 5,593,847. Monitoring of NCA 50/90 in blood samples of beast cancer patients.
- Allard, W. J., Obzansky, D. M., Pankratz, T. J., and Vaidya, H. C. 1997. US Patent 5, 654,159. Assay with signal detection in the presence of a suspended solid support.
- Allard, W. J., Obzansky, D. M., Pankratz, T. J., and Vaidya, H. C. 1995. US Patent 5,434,051. Assay with signal detection in the presence of a suspended solid support.

### **PUBLICATIONS**

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Cristofanilli M, Hayes DF, Budd GT, Ellis MJ, Stopeck A, Reuben JM, Doyle GV, Matera J, Allard WJ, Miller MC, Fritsche HA, Hortobagyi GN, and Terstappen LWMM. 2005. Circulating Tumor Cells: a Novel Prognostic Factor for Newly Diagnosed Metastatic Breast Cancer. *JCO* 23:1420-1430.

- Moreno JG, Miller MC, Gross S, Allard WJ, Gomella LG, and Terstappen LWMM. 2005. Circulating tumor cells predict survival in patients with metastatic prostate cancer. *Urology* 65: 713-718.
- Cristofanilli M, Budd GT, Ellis MJ, Stopeck A, Matera J, Miller MC, Doyle GV, Allard WJ, Terstappen LWMM, Hayes DF. 2004. Correlation of Circulating Tumor Cells With Progression and Survival in Metastatic Breast Cancer. New England J Med. 351:781-791.

[------] Manuscript submitted.

- Allard WJ, Matera J, Miller MC, Repollet M, Connelly MC, Rao C, Tibbe AGJ, Uhr JW, Terstappen LWMM. 2004. Tumor cells circulate in the peripheral blood of all major carcinomas but not in healthy subjects or patients with non-malignant diseases. Clin Cancer Research. 10:6897-6904.
- Kagan M., Howard M.S., Bendele T., Mayes J., Silvia J., Repollet M., Doyle J., Allard J. et al. 2002. A sample preparation and analysis system for identification of circulating tumor cells. J Clin Ligand Assay, 25:104-110.
- Lipton A, Ali SM, Leitzel K, Demers L, Chinchilli V, Engle L, Harvey HA, Brady C, Nalin CM, Dugan M, Carney W, Allard J. 2002. Elevated serum Her-2/neu level predicts decreased response to hormone therapy in metastatic breast cancer. J Clin Oncol, 20(6):1467-72.
- Ali, S.M., Leitzel, K., Chinchilli, V., Engle, L., Demers, L., Harvey, H., Carney, W., Allard, J., and Lipton, A. 2002. Relationship of serum HER-2/neu and serum CA 15-3 in patients with metastatic breast cancer. Clin Chem., 48(8):1314-20.
- Lipton A., Ali, S.M., Leitzel, K., Demers, L., Chinchilli, V., Engle, L., C. Brady C., Nalin, C.M., Dugan M., Carney W., and Allard J. 2002. Elevated Serum HER-2/neu Level Predicts Decreased Response to Hormone Therapy in Metastatic Breast Cancer. J Clin Oncology 20(6):1467-1472.
- Okihara K., Fritsche H.A., Ayala A., Johnston D.A., Allard W.J., and Babaian R.J. 2001. Can complexed prostate specific antigen and prostatic volume enhance prostate cancer detection in men with total prostate specific antigen between 2.5 and 4.0 ng./ml. J Urol 165:1930-1936.
- Cook, G.B., Neaman, I.E., Goldblatt, J.L., Cambetas, D.R., Hussain, M., Luftner, D., yeung, K.K., Chan, D.W., Schwartz, M.K., and Allrd W.J. 2001. Clinical utility of serum HER-2/neu testing on the Bayer Immuno 1 automated system in breast cancer. Anticancer Res. 21(2B):1465-1470.

- Brawer, M.K, Cheli, C.D., Neaman, I.E., Goldblatt, J., Smith C., Schwartz, M.K., Bruzek, D., Morris, D.L., Sokoll, L., Chan D.W., Yeung, K.K., Partin, A. and Allard, W.J. 2000. Complexed PSA provides significant enhancement of specificity compared with total PSA for detecting prostate cancer. J Urol 163:1476-1480.
- Payne RC, Allard JW, Anderson-Mauser L, Humphreys JD, Tenney DY, Morris DL. 2000. Automated assay for HER-2/neu in serum. Clin Chem, 46(2):175-82.
- Allard, W.J., Cheli, C.D., Morris, D.L., Goldblatt, J., Pierre, Y., Kish, L., Dai, J., Vessella, R.L., Chan, D.W., Schwartz, M.K., Zhou, Z., and Yeung, K.K. 1999. Multicenter evaluation of the performance and clinical utility in longitudinal monitoring of the Bayer Immuno 1<sup>™</sup> complexed PSA assay. Int. J. Biol. Markers, 14:73-83.
- Zhou Z, Barnett T.R., Very D.L. Jr, Ng P.C., Pellegrino C.M., Davis G., Belenky A., Allard W.J., Yeung K.K. 1999. Analysis of monoclonal antibodies to prostate-specific antigen: reactivity with native and recombinant prostate-specific antigen. Tumour Biol, 20 Suppl 1:86-93.
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- Cheli, C.D., Morris, D.L., Neaman, I.E., Dai, J., Allard, W.J., and Yeung, K.K. 1999. Measurement of four tumor marker antigens in the sera of pregnant women. J. Clin. Lab. Anal. 13:35-39.
- Allard, W.J., Zhou, Z, and Yeung, K.K. 1998. Novel Immunoassay for the measurement of complexed PSA in serum. Clin. Chem. 44(6):1216-1223.
- Brawer, M.K., Meyer, G.E., Letran, J.L., Bankson, D.D., Morris, D.L., Yeung, K.K. and Allard, W.J. 1998. Measurement of complexed PSA improves specificity for early detection of prostate cancer. Urology, 52:372-278.

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- Cheli, C.D., Morris, D.M., Kish, L., Goldblatt, J., Neaman, I., Allard, W.J., et al. 1998. Bayer Immuno 1<sup>™</sup> CA 15-3 assay: a highly precise and fully automated immunoassay for longitudinal monitoring of CA 15-3 assay levels in serum. Clin. Chem. 44(4):765-772.
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- Allard, W.J., Neaman, I.E., Elting, J.J., Barnett, T.R., Yoshimura, H., Fritsche, H.A., and Yeung, K.K. 1994. Nonspecific cross-reacting antigen 50/90 is elevated in patients with breast, lung, and colon cancer. Cancer Res. 54:1227-1234.
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- Nabel, G., Bucalo, L. R., Allard, J., Wigzell, H., and Cantor, H. 1981. Multiple activities of a cloned cell line mediating natural killer cell function. J. Exp. Med. 153:1582.

#### Abstracts

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- Hayes DF, Miller MC, Cristofanilli M, Ellis MJ, Stopeck A, Allard WJ, Matera J, Doyle GV, Terstappen LWWM, and Budd GT. Circulating tumor cells are a reliable predictor of progression free survival and overall survival during therapy of patients with metastatic breast cancer. *Breast Cancer Research and Treatment* 88(1): S225 (A6015), 2004.
- Cristofanilli M, Hayes DF, Rueben JM, Budd GT, Ellis M, Stopeck A, Miller MC, Matera J, Allard WJ, Fritsche HA, and Terstappen LWMM. Detection of circulating tumor cells (CTCs) is a prognostic factor in first-line metastatic breast cancer (MBC). *Breast Cancer Research and Treatment* **88(1)**: S225 (A6016), 2004.
- Budd GT, Cristofanilli M, Terstappen LWWM, Ellis MJ, Stopeck A, Allard WJ, Matera J, Miller MC, Doyle GV, and Hayes DF. Correlation of changes in circulating

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- Hayes DF, Cristofanilli M, Budd GT, Ellis M, Stopeck A, Matera J, **Miller MC**, Doyle GV, Allard WJ, and Terstappen LWMM. Monitoring circulating tumor cell (CTC) levels to predict rapid progression in metastatic breast cancer (MBC): A prospective, multi-institutional trial. *Proc Annu Meet Am Soc Clin Oncl* **23**: 5 (A509), 2004.
- Cohen SJ, Alpaugh RK, Allard WJ, Cheng JD, Gross ST, Lewis NL, et al. 2003. Isolation and characterization of circulating tumor cells in patients with colorectal cancer. ASCO Abstract 1186.
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- Hayes DF, Cristofanilli M, Budd GT, Ellis M, Stopeck A, Matera J, Miller MC, Doyle GV, Allard WJ, and Terstappen LWMM. Monitoring circulating tumor cell (CTC) levels to predict rapid progression in metastatic breast cancer (MBC): a prospective, multi-institutional trial. *J Biol Markers* 19(S3): S26, 2004.
- Allard WJ, Hayes DF, Repollet MI, Rao C, Hermann ML, Metara J, Miller MC, and Terstappen LW. A cellular preservative improves the specificity and yield of circulating tumor cells in carcinoma patients. *Proc Annu Meet Am Soc Clin Oncl* 22: 866 (A3482), 2003.
- Allard, W.J., Cheli, C.D., Neaman, I.E., Goldblatt, J., Morris, D.L., Smith, C., Schwartz, M.K., Bruzek, D., Sokoll, L., Yeung, K.K., et al. 1999. Complexed PSA and free to total PSA ratio provide equivalent specificity but would save biopsies in different patient populations. Clin. Chem. 45:A106.

- Cheli, C.D., Yeung, K.K., Brawer, M.K., and Allard, W.J. 1999. Complexed PSA (cPSA) has clinical utility in the early detection of prostate carcinoma in men with total PSA values less than 4.0 ng/ml. Clin. Chem. 45:A107.
- Cheli, C.D., Yeung, K.K., Brawer, M.K., and Allard, W.J. 1999. Proportions of free and complexed PSA and their relation to stage and grade of prostate carcinoma: percent free PSA increases in some patients with late stage disease. Clin. Chem. 45:A107.
- Neaman, I.E., Cheli, C.D., Goldblatt, J., Pierre, Y., Kish, L., Chen, Y., Dai, J., Zhou, Z., Yeung, K.K. Allard, W.J. et al. 1999. Multicenter evaluation of the analytical and clinical performance of the Bayer Immuno 1<sup>™</sup> complexed PSA assay. 1999. Clin. Chem. 45:A107.
- Cook, G.B., Cheli, C.D., Neaman, I.E., Goldblatt, J., Schwartz, M.K., Loughlin, K.R., Fritsche, H.A., Babaian, R.J., Yeung, K.K., Allard, W.J. et al. 1999. The Bayer Immuno 1<sup>™</sup> PSA assay is a clinically useful test for the detection of prostate carcinoma: a multicenter evaluation. Clin. Chem. 45:A108.
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